K102207

510(k) Summary

NOV 23 2010

This revised summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date

November 11, 2010

Repackager / Relabeler

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Trade/Proprietary Name:

Fiber Force products (repackaged product of Fast Splint):

Pink/white Mesh (118mmx53mm), Pink/white UD Fiber (2mmx150mm), Pink/white Braided Rope (1mmx150mm), Pink/white Braided Rope (2mmx150mm), Light Cure Pink/white Resin (3ml + 4tips)

Common or Classification Name

Glass fiber reinforcement material for Denture relining, repairing, or rebasing resin (21CFR 872.3760, Product code EBI, Class2)

Description:

Fiber Force is a system of light-cured resin pre-impregnated E-glass fibers used for reinforcement in a variety of applications in dentistry. All formats of Fiber Force use specially treated E-glass fibers that impregnated in resin using an industrialized process that ensures homogeneity with the acrylic or composite resin interface material.

Indication for use:

- As structural reinforcement for fabricating and/or repairing removable prostheses (dentures) and removable implant supported dentures (ISDs)
- As reinforcement for temporary and/or permanent plastic/composite partial and full crowns and bridges.
- As reinforcement for customized splints used to immobilize teeth which may be required for orthodontia, periodontia, traumatology and any dental activity requiring bonding of natural teeth.

Predicate Device:

Manufacturer	: Stick Tech., Ltd.
Device	: everStick/ everStick Net
510(k) Number	: K011788 (Nov. 05, 2001)/K011799 (Nov.05, 2001)

Substantial Equivalence:

Fiber Force described in this 510(k) has the same intended use and similar technical characteristics as everStick / everStick Net of Stick Tech Ltd.

The indications for use, material, form factor, performance, and safety characteristics between Fiber Force and the predicate device are the same. The primary difference is size, packaging,

structure only. Accordingly we can claim the substantially equivalence of Fiber Force to the predicate device.

Technological Characteristics

The following tests were performed according to standard ISO 10993-1, ISO 10993-5 and ISO 7405 and the product is tested to be safe and has the same technological characteristics as the predicate device since both have same indications for use, similar polymers composition and same working technique;

1. **Biological Evaluation**

According to the standards applicable to biocompatibility evaluation, PRP's belong to the category of devices in contact with a surface (mucous membranes) in the case of *Clinical* application and to that of devices without contact in the case of *Laboratory* application (in this latter case, biological development is not requested). The medical device and its many applications have been described, particularly the components of the formulation, the impurities, the leachable products and degradation. The initial evaluation tests taken into consideration for the Clinical application were: cytotoxicity, sensitization, intradermal irritation or reaction, subchronic and subacute toxicity and genotoxicity. We have also decided to perform additional tests, such as carcinogenicity and toxicity on reproduction and development, in order to have an in-depth evaluation of our product. The study of these toxicological risks showed that it is improbable that they cause unacceptable health risk. The formulation, optimized to achieve effective polymerization, minimizes the leaching of soluble products into the water in the oral environment. The cytotoxicity test performed by an outside agency proved the total absence of cytotoxicity of the reticulated product.

However, the following risks were able to be identified:

- irritation or sensitization (allergy) during contact with the non-polymerized resin with the fingers of certain predisposed practitioners,
- mechanical irritation due to airborne glass fibers during cutting of the product.

These risks can be eliminated by taking precautions such as wearing gloves, protective goggles, and a mask, and by grinding under water or with surgical aspiration during cutting or elimination of the product. Also, the existence of these risks was mentioned in the instructions for use, as well as precautions to take to avoid them. To the best of our knowledge, we have not identified any major or unacceptable risks associated with the PRP product, by ensuring that the instructions for use are scrupulously respected.

2. **Vitro Cytotoxicity**

An *in vitro* biocompatibility test on the "Fiber Force" removable denture reinforcement, RES reference prp L018A was performed with the goal of determining the cytotoxic potential. This study was conducted according to the requirements of the standard NF EN ISO 10993: Biological Evaluation of Medical Devices, Part 5: Tests concerning *in vitro* cytotoxicity.

Under the conditions of this study, the extract of the tested product did not provoke any sign of cell lysis or toxicity (reduction of the cellular density lower than 25%). The extract of the tested product satisfied the test requirements. The positive and negative controls were compliant with the expected results.

Chemical Component Data: Chemical component data for Fiber Force including CAS number is described in the product description.

Non-clinical Considerations: Safety and Effectiveness of the Subject Device

The fiber used is fiberglass E, the same composition as the fiberglass E used for manufacturing of Postec and Precipost posts by BCM since 2001. UDMA and TEGDMA monomers are very common in dentistry and have been used for more than 30 years particularly for filling products, adhesives, etc. The camphorquinone is the photocatalyst best adapted to the spectra of dental photopolymerization lamps and housing. It is found in the photopolymerizable dental materials for more than 15 years. Ethyl-4-(dimethylamino)-benzoate is a polymerization accelerator which is

found in several other dental products, particularly Dyract, an adhesive of De Trey Dentsply, which is not cytotoxic (67) and has never been the subject of a health alert (35).

The blue pigment (Ultramarine blue) is used in the coloring of cosmetic products (make-up and mascara) and is universally accepted for the coloring of objects intended for contact with food and for the manufacturing of toys.

The white pigment (titanium dioxide) is used for food coloring (E171) in cosmetics, medications and in the European and US pharmacopoeia.

The red pigment (iron oxide (red M)) is accepted for manufacturing of toys (in Europe according to EN71/3 and in the USA according to the ASTM), and for the coloring of objects intended for contact with food (Germany, Austria, and Australia). The red pigment S is iron oxide III. This latter is a food additive of which the ADI (*acceptable daily intake*) is 0.5mg/kg (18).

The four pigments, the silica, the camphorquinone and the TEGDMA are already in use since 1996 by BCM for the manufacturing of the product Vectris. It is also a photopolymerizable pre-impregnated fiber intended for the manufacturing of dental crowns and bridges: it is recovered and buried in various reconstitution resins. The chemical formulation, whose photocatalysts are used for the photopolymerization of PRP, is identical to that used in composite filling products, for example TETRIC EVO CERAM from the IVOCLAR Company. (79) For this product, the thickness of the product, fully hardenable using a photopolymerizing office lamp is greater than 2 mm (enamel shade transparent) and 1.5 mm for strongly colored products (dentine shade). A study by Prof. Antonio CERUTTI over six and twelve months showed excellent stability of the ingredients used for TETRIC EVO CERAM when they were polymerized for 10 seconds with a high intensity lamp (1200mw) and 20 seconds with an average lamp(700mW). (80)

The study is also based on the product VARIOLINK II (86) or ultra from the IVOCLAR Company (90): it is a photo- and auto-polymerizable composite (dual cure), radio-opaque for adhering restorations. It is found in the non-polymerized state and is thus in contact with l mineral and gingival or pulpal tissues. (86)

The formulation contains compounds similar to our PRP product (UDMA, TEGDMA).

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Synca Marketing Ltd. concludes that Fiber Force is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synca Marketing, Incorporated
C/O Mr. Dave Kim
MTech Group
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Houston, Texas 77079

NOV 23 2010

Re: K102207
Trade/Device Name: Fiber Force products (repackaged product of Fast Splint)
Regulation Number: 21 CFR 872.3670
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: November 15, 2010
Received: November 15, 2010

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S.,M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV 2 3 2010

510(K) Number (if known): K10 2207

Device Name: **Fiber Force products (repackaged product of Fast Splint):** Pink/white Mesh (118mmx53mm), Pink/white UD Fiber (2mmx150mm), Pink/white Braided Rope (1mmx150mm), Pink/white Braided Rope (2mmx150mm), Light Cure Pink/white Resin (3ml + 4tips)

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• As reinforcement for customized splints used to immobilize teeth which may be required for orthodontia, periodontia, traumatology and any dental activity requiring bonding of natural teeth.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner/

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102207